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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,837	10/26/2001	David S. Soane	ALNS-002PN	7838

23979 7590 04/20/2004

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EXAMINER


NUTTER, NATHAN M

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/055,837	Applicant(s) SOANE ET AL. 	
	Examiner Nathan M. Nutter	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 0204.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33 and 53-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33 and 53-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of the species of a carbohydrate for the head group, acrylamide for the cross-linking group, the specific monomer being glucose-2-acrylamide, and the polymeric network having from 1 to a 100 target binding sites, and, the sites bind to a protein, claims 33 and 53-86, in the Paper filed 28 January 2004 is acknowledged. The traversal is on the ground(s) that "under 37 CFR § 1.141(a), they are entitled to claim...more than one species of an invention...in one national application".

This is not found persuasive because of the sheer multitude of possible combinations, each requiring separate consideration and time. Counsel fails to delineate why an undue burden of search would be placed upon the Examiner to search all species. Nor has counsel submitted evidence or identified such evidence now of record showing the species to be obvious variants or clearly admitted on the record that this is the case. Clearly, an undue burden would be placed upon the Examiner to examine all species.

However, after a search for the elected species, the search has been broadened and the requirement is, thus, removed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 33, 53-86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants' claims are directed to synthetic polymer complements (SPCs) that are *soluble*. The present application fails to describe sufficient examples of *soluble*

SPCs that are within the scope of the presently claimed invention. Applicants' claimed scope of compounds represents only an invitation to experiment regarding possible compounds. It is not clear what the bounds of "soluble" encompass or how the claimed SPCs lie within the bounds of "soluble" compounds. It is impossible to determine which, if any, of applicants' examples are "soluble" SPCs and, thus, to determine if applicant was in possession of the full scope of "soluble" SPCs, as now claimed. Adequate disclosure, like enablement, requires representative examples that provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possesses the alleged utility and additionally demonstrate that *applicants had possession of the full scope of the claimed invention*. See *In re Riat et al* (CCPA 1964) 327 F2nd 685, 140 USPQ 471; *In re Barr et al* (CCPA 1971) 444 F2nd 349, 151 USPQ 724 (regarding enablement) and *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2nd 1398, decided 22 July 1997; No. 96-1175) (regarding disclosure). The more

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unpredictable the art, the greater the showing required (e.g. by "representative examples") for both enablement and adequate disclosure.

The separate parts that make up applicants' "soluble" SPCs, i.e., the monomers, cross-linking groups, co-surfactants, targets and/or active agents, could encompass very different moieties and the size limitations on the SPCs would seem to be difficult to determine for soluble compounds. Additionally, the description of "soluble" in the Specification (see page 46, 2nd paragraph) is not adequate to show possession of the claimed invention. The disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Moreover, the claimed genus encompasses members that are yet to be prepared or envisioned. This further evidences that the instant disclosure does not constitute support for the claimed genus or a substantial portion thereof.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33 and 53-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite composition comprising synthetic polymer complements (SPCs) that are *soluble*, without clearly specifying into what solvent(s) the SPCs may be soluble. The concept "solubility" is relative, not only to solvent, but also temperature and concentration of the solute. As such, the instant claims are

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deemed to be vague and confusing since the actual metes and bounds of the claims cannot be clearly ascertained.

Further, the claims are drawn to SPCs having "a diameter less than about 1000 nm". Since the claims recite that these SPCs are soluble, the diameter limitation is deemed to be vague and indefinite since it is not clear how this measurement is performed. Does this become the diameter in solution or the diameter of dried particulate SPCs? Further, if this is the diameter in solution, what solvent(s) must be employed?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined

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under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 33, 53, 54, 57-59, 61, 62, 65, 67 and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Dordick et al (U.S. 5,914,367), previously cited by the applicants.

Dordick et al teach "a method of preparing a polymer-protein composite" by polymerizing a monomer "in the presence of a protein dissolved in an organic phase via ion-pairing of the protein with a surfactant. Note the Abstract and Figure 1. note column 1 (lines 16-28) for the utility, including binding of constituents to the produced composite structures. The reference teaches that the enzyme is employed as the target and is modified with acryoyl chloride and acrylic acid. Note column 13 (line 55) to column 14 (line 25). Methyl methacrylate is used as a co-monomer and a trimethacrylate is the cross-linker in the polymerization. Figure 1 shows that a polymer network forms around the enzyme. The reference teaches the essential solubility at Example V. Since the materials employed and the end-product are essentially identical, the claimed particle size would inherently be identical.

Claims 33, 53, 54, 57-59, 61-65, 67 and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Singh (U.S. 5,663,387), previously cited by the applicants.

The patent to Singh teaches the manufacture of polymerized liposomes that contain enzymes. Note the Abstract and Figure 1. The liposomes are

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composed of two or more lipid monomers having polymerizable functionalities included with at least one of the lipid monomers being capable of metal chelating. Note column 3 (lines 1-54) and column 4 (lines 13-29). The liposomes of the reference immobilize an enzyme via hydrogen bonds and/or electrostatic interactions using metal ions. Note column 22 (lines 36-68). The liposomes are being interpreted to read on the soluble SPCs herein claimed. Although the size limitations of the liposomes are not disclosed, since the materials and end-product appear to be identical to those claimed herein, the size would be an inherent property of such liposomes, absent evidence to the contrary.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33, 53-59, 61-70 and 72-86 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Arnold et al (U.S. 5,310,648), previously cited by the applicants.

The reference to Arnold et al teaches the manufacture of an "imprinted matrix" that binds a predetermined molecule through selective binding interactions. Note the Abstract. Specifically, "fluid" imprinted matrices (i.e. liposomes) are disclosed. Note Example XII> the Examiner interprets a liposome

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to read on the soluble SPCs claimed. Polymerizable monomers that contain an iminoacetic acid metal chelating group are included. Note compound I in columns 15 and 16. these monomers bind a metal ion which in turn binds a template protein. Note column 19 (lines 9-45) and column 5 (lines 45-68). Amphiphiles containing a phosphate head group and polymerizable groups are disclosed that are used in conjunction with the metal binding monomers. Note column 19 (lines 9-11). The polymerization is accomplished with UV radiation. Note column 19 (lines 36-40). Although the size limitations of the liposomes are not disclosed, since the materials and end-product appear to be identical to those claimed herein, the size would be an inherent property of such liposomes, absent evidence to the contrary.

Although the reference fails to disclose making their polymer by the exact same process steps as those claimed, it would be obvious to one of ordinary skill in the art since this was an established method for making such liposomes at the time the invention was made.

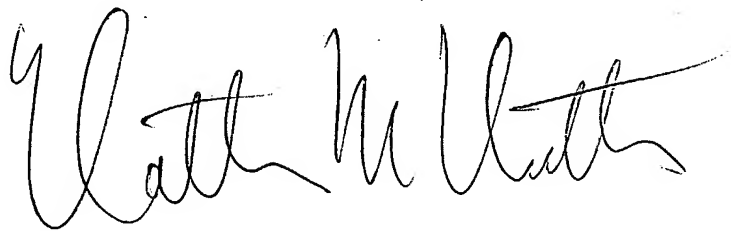
The imprinted matrix of Arnold et al meets all of the limitations of the synthetic polymer complements of the instant claims except for the product-by-process limitations and would either anticipate or render obvious the claimed polymer. Since all of the claims are drawn to a "synthetic polymer complement", that any polymer that falls within the product limitations of the claimed SPCs reads on this product. The process by which the claimed polymer is made does not appear to lend patentable weight to the invention. One of ordinary skill in the art would expect the polymers to be identical no matter how synthesized.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan M. Nutter whose telephone number is 571-272-1076. The examiner can normally be reached on Monday-Friday 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James J. Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Nathan M. Nutter', with a stylized, cursive script.

Nathan M. Nutter
Primary Examiner
Art Unit 1711

nmn

16 April 2004